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Plaintiff Healthier Choices Management Corp. (“Healthier Choices”) respectfully submits this response in Opposition to Defendants Philip Morris USA, Inc. (“PMI”) and Philip Morris Products S.A.’s (“PMP”) (collectively, “Defendants”) Motion for Attorneys’ Fees Under 35 U.S.C. § 285 (Dkt. No. 58).

I. INTRODUCTION

Defendants’ request for attorneys’ fees should be denied on the face of the Motion for at least three reasons. *First*, there is simply no need for the Court to resolve the Motion while Healthier Choices’ appeal is pending in the Federal Circuit. Courts *routinely* defer resolution of such motions pending the outcome of an appeal. Such an expedient resolution would greatly serve judicial economy, allowing the appeal to be resolved without the Court delving into contingent issues that it may likely never need to decide.

Second, this is not the “rare case” that would justify the imposition of attorneys’ fees under § 285. There is nothing “exceptional” about a straightforward case that was resolved at the pleading stage, and the cases cited by Defendants in support are wholly inapposite.

Finally and most importantly, Healthier Choices’ litigation position and litigation conduct has at all times been *reasonable*. Healthier Choices’ pleadings specifically alleged that Defendants’ e-cigarette device infringes its patent because it initiates a combustion reaction. Indeed, Healthier Choices undertook independent testing to confirm that the accused device *in fact* initiates a combustion reaction.

Notwithstanding, Defendants contend that Healthier Choices should never have sought to vigorously enforce its patent because Defendants previously stated in an application to the U.S. Food and Drug Administration (“FDA”) that its device did not cause combustion. Thus, Defendants contend that Healthier Choices should have known that Defendants’ own self-serving statements in that application would be credited *over* Healthier Choices’ specific allegations in its pleadings and the results of its independent testing.

As discussed in depth below, it was error for this Court to credit Defendants’ statements as true over the contrary specific allegations in Healthier Choices’ pleadings. That is true even when Defendants’ self-serving statements were attached as an exhibit to the Complaint, but *especially* when the Amended Complaint removed those exhibits. Courts have specifically warned that “it would be perverse” for courts to use a defendant’s “self-serving claims to reject [a plaintiff’s] factual allegations,” merely because they were attached to the complaint. *Haskett v. T.S. Dudley Land Co.*, 648 F. App’x 492, 496–97 (5th Cir. 2016). That is precisely what happened here—twice, and even when those “self-serving claims” were *not* attached to the complaint. It is all the more perverse for Defendants to actually seek exceptional fees on this basis. Thus, Defendants’ Motion should be denied.

II. BACKGROUND

Healthier Choices commenced this action for patent infringement on November 30, 2020. Healthier Choices is the owner of U.S. Patent No. 10,561,170

(“the ’170 patent”). The ’170 patent sets forth specifications for an electronic pipe that can be used, *inter alia*, to deliver nicotine to users. As set forth in independent claim 1 and independent claim 5 of the ’170 patent, the electronic pipe does so by transmitting an electronic current from a battery to a heating element that initiates a combustion reaction.

The Complaint alleges that Defendants manufacture, distribute, market, and sell an electronic cigarette, the IQOS system, that directly or indirectly infringes the ’170 patent, either literally or under the doctrine of equivalents. Defendants market the IQOS system as a device that heats tobacco at temperatures of up to 350 degrees without burning. The critical issue in this case was whether Healthier Choices plausibly alleged that the IQOS system initiates at least a partial combustion reaction in the IQOS system to survive a motion to dismiss.

Throughout the Complaint, Healthier Choices alleged that the IQOS system initiates a combustion reaction. *E.g.*, Compl., Dkt. No. 1, ¶¶ 46, 52 (“activating the heating element of the Accused Infringing Product after insertion of an IQOS® Tobacco Stick generates a combustion reaction”). In support of the Complaint, Healthier Choices attached as Exhibit J a document drafted *by Defendants*—a Modified Risk Tobacco Product Application (“MRTPA”) that Defendants submitted to the FDA. Although the MRTPA includes self-serving statements by Defendants that combustion does not occur, Healthier Choices included this document because it also contains certain admissions by Defendants indicating that combustion does in

fact occur. *See, e.g.*, Compl., Ex. J at 40–41 (describing Defendants’ testing showing the presence of two important combustion markers, nitrogen oxides and carbon monoxide, indicating that at least some combustion occurs).

After receiving two extensions of time, Defendants moved to dismiss the Complaint on February 25, 2021. The Court granted the motion to dismiss on July 23, 2021. In critical part, the Court found that because Healthier Choices attached Defendants’ MRTPA to the Complaint, it could not contradict any of Defendants’ self-serving statements in that exhibit. Order Granting Motion to Dismiss, Dkt. No. 42, at 17 (“[T]he Court must accept as true only those well-pled facts that do not conflict with Exhibit J.”). As such, because Defendants stated in the MRTPA that no combustion occurs, the Court accepted this as true notwithstanding any contrary allegations in the Complaint. *Id.* Moreover, the Court found that it was not impermissibly engaging in claim construction regarding the term “combustion reaction” because Healthier Choices did not show that “there is a dispute as to the construction of that term” (*id.* at 18), and that in any event the term must include the claim limitation that “some sort of combustion must occur.” *Id.* at 19. Again, because Defendants’ MRTPA stated no combustion occurs, the Court accepted as conclusive that no combustion reaction occurs, and dismissed the Complaint on that basis.

Healthier Choices filed a motion for leave to file an Amended Complaint on August 6, 2021, attaching a proposed Amended Complaint as an exhibit. Dkt. No.

47-2 (“Am. Compl.”). The Amended Complaint removed Defendants’ MRTPA as an exhibit, in an effort to prevent Defendants’ inaccurate and one-sided descriptions from being deemed irrefutable facts simply by virtue of being attached to a pleading. Moreover, the Amended Complaint attaches and incorporates throughout the Declaration of Michael J. Deible, Ph. D., who performed testing on the IQOS device and provided an independent opinion that combustion does in fact occur in the device. *E.g.*, Am. Compl., Ex. B, ¶ 4 (“In my opinion, based on the testing and analysis I performed and my review of the technical literature, the IQOS device causes combustion of a HeatStick tobacco product when it is operated in accordance with its instructions for use.”); *id.* ¶ 12 (“Combustion is a chemical reaction that requires fuel, oxygen and an ignition source, each of which is present during the normal operation of an IQOS device with a Marlboro HeatStick tobacco product.”) *id.* ¶ 13 (“Combustion was observed by the generation of heat, and the formation of carbon monoxide (CO), carbon dioxide (CO₂), and carbonaceous materials (C(s)) in air while no significant heat was generated in an inert (e.g., N₂) atmosphere.”). Again, Healthier Choices alleged that the IQOS system causes a combustion reaction throughout its Amended Complaint. *E.g.*, Am. Compl. ¶ 46 (alleging that “the IQOS® system results in combustion of at least a portion of the HeatStick”); *id.* ¶¶ 47–49 (“the IQOS® system initiates a combustion reaction in the chamber of the system”); *id.* ¶ 49(c). (“A thermogravimetric analysis-differential scanning calorimetry (‘TGA-DSC’) analysis of a HeatStick evidences an exothermic reaction

between 250°C and 340°C and therefore, a combustion reaction[.]”); *id.* ¶ 55 (“activating the heating element of the IQOS® system after insertion of a HeatStick generates a combustion reaction”).

The Court denied Healthier Choice’s motion for leave to file an Amended Complaint on December 3, 2021. The Court acknowledged that the filing of the Amended Complaint rendered the original Complaint “of no legal effect,” and that it could not “weigh the evidence of combustion and make a factual determination as to whether combustion occurs.” Order Denying Leave, Dkt. No. 52, at 6–7 (brackets and quotation omitted). Notwithstanding, the Court found that it could still consider the removed exhibits that were previously attached to the original Complaint—including Defendants’ MRTPA and an FDA press release¹—because it found that these documents were central to Healthier Choices’ patent infringement claims. *Id.* at 10–12.

Because the Court concluded that it could again *consider* these exhibits, the Court concluded that all of the statements in the now-removed exhibits *must also be accepted as conclusive facts* that could not be contradicted by the Amended Complaint—including Defendants’ self-serving assertions regarding the lack of combustion. *Id.* at 12–13. Thus, the Court held that, regardless of whether

¹ The FDA press release was previously attached to the original Complaint as Exhibit B. Nowhere does the Court’s Order Granting Defendants’ Motion to Dismiss refer to this Exhibit which, in any event, was not attached to the Amended Complaint.

Defendants’ MRTPA was attached to the Amended Complaint, Healthier Choices’ specific and well-pled facts could not contradict Defendants’ own assertions about its product. Given that, the Court denied Healthier Choices leave to file the Amended Complaint because it could not plausibly allege that combustion occurs. *Id.* at 13. Nowhere did the Court address Dr. Deible’s declaration and the related allegations in the Amended Complaint regarding his testing confirming that a combustion reaction does *in fact* occur because, presumably, such testing would contradict Defendants’ self-serving statements in its application papers.

Healthier Choices timely filed a notice of appeal on December 14, 2021. On December 16, 2021, Defendants filed a Motion for Attorneys’ Fees pursuant to 35 U.S.C. § 285. Defendants filed under seal affidavits and documentation in support of the requested award on January 18, 2022.

III. LEGAL STANDARD

Section 285 provides that “[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party.” 35 U.S.C. § 285. “The Supreme Court has characterized § 285 as a safeguard and has stressed that district courts have the authority and responsibility to ensure frivolous cases are dissuaded.” *Stone Basket Innovations, LLC v. Cook Med. LLC*, 892 F.3d 1175, 1183 (Fed. Cir. 2018) (brackets and quotations omitted) (citing *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 647 (2015)). As such, “a district court may award fees in the rare case in which a party’s unreasonable conduct—while not necessarily independently

sanctionable—is nonetheless so ‘exceptional’ as to justify an award of fees.” *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 555 (2014).

An “exceptional case” for purposes of § 285 is “one that stands out from others with respect to the substantive strength of a party’s litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated.” *Id.* at 554. “This analysis considers the case based on the totality of the circumstances, requiring a movant to show the case is exceptional by a preponderance of the evidence.” *Munchkin, Inc. v. Luv n’ Care, Ltd.*, 960 F.3d 1373, 1378 (Fed. Cir. 2020). The purpose of § 285 “is to prevent a party from suffering a gross injustice, not to punish a party for losing,” and as such Courts “do not award attorney’s fees as a penalty for failure to win a patent infringement suit.” *Id.* (internal quotations and citations omitted).

IV. ARGUMENT

A. The Court Should Defer Ruling on Defendants’ Motion Pending the Outcome of Plaintiff’s Appeal

As a threshold matter, the Court need not—and should not—resolve Defendants’ Motion while an appeal is pending that may very well moot the issue. The Court should instead defer resolution of the Motion pending the outcome of Healthier Choices’ appeal, which may likely obviate the need for the Court to resolve this Motion in the first place. Deferring resolution of the Motion until after

Plaintiff's appeal is resolved will not prejudice any party and will greatly serve judicial economy.

The Court has discretion to defer ruling on any motion for attorneys' fees, including those made under § 285, pending the outcome of an appeal. Indeed, the Advisory Committee Notes to the 1993 amendments to Fed. R. Civ. P. 54 explain: "If an appeal on the merits of the case is taken, the court may rule on the claim for fees, may defer its ruling on the motion, or may deny the motion without prejudice, directing ... a new period for filing after the appeal has been resolved." As such, courts routinely dismiss without prejudice motions for attorneys' fees pending the outcome of an appeal. *E.g.*, *Cross v. EquityExperts.org, LLC*, 2020 WL 11191758, at *2 (N.D. Ga. Aug. 3, 2020) ("Instead of resolving Plaintiffs' motion [for attorneys' fees] during the pendency of the appeal, justice and efficiency are better served at this point by denying the motion without prejudice and granting Plaintiffs leave to re-file the motion after the conclusion of the appeal."); *BASF Corp. v. SNF Holding Co.*, 2019 WL 3554699, at *11 (S.D. Ga. Aug. 5, 2019) (dismissing without prejudice motion for attorneys' fees made under § 285 pending resolution of Federal Circuit appeal); *Baggage Airline Guest Servs., Inc. v. Roadie, Inc.*, 2019 WL 644827, at *2 (D. Del. Feb. 15, 2019) (same); *Sprint Commc'ns Co. L.P. v. Comcast Cable Commc'ns, LLC*, 201 F. Supp. 3d 564, 566 (D. Del. 2016) (same); *Certusview Techs., LLC v. S & N Locating Servs., LLC*, 2015 WL 3466842, at *2 (E.D. Va. June 1, 2015) (same).

Here, deferring resolution of Defendants’ Motion is plainly warranted. *First*, the Federal Circuit’s resolution of the appeal may likely render Defendants’ Motion moot. As such, any determination of whether this is an “exceptional” case warranting attorney’s fees—and if so, whether the fees sought are reasonable—may very well end up being a wasted effort. *See BASF Corp.*, 2019 WL 3554699, at *11 (“[D]eferring until such appellate decision issues will obviate the possibility of the Court having to revisit this matter. If the Federal Circuit rules in Plaintiff’s favor, any award of costs by this Court to the prevailing party would be rendered null, and the Court would have to readdress this issue following appeal.”); *Baggage Airline Guest Servs., Inc.*, 2019 WL 644827, at *1 (“It is entirely possible that the Federal Circuit could reverse the judgment in this case, thereby moot[ing] the fees motion.”) (citation omitted); *Liberty Mut. Fire Ins. Co. v. State Farm Fla. Ins. Co.*, 2018 WL 9708621, at *2 (S.D. Fla. Sept. 5, 2018) (“There is nothing in the record that shows good cause for the Undersigned and the Court to decide the attorney’s fees and costs issue when the entitlement and amount could change once the appeal is decided.”).

Moreover, deferring resolution of Defendants’ Motion is particularly appropriate here, given the “interrelation of the appellate court’s ultimate ruling and [Healthier Choices’] defense against Defendants’ request for attorneys’ fees—that it advanced a ‘substantively strong’ infringement action grounded in sound legal and factual basis.” *BASF Corp.*, 2019 WL 3554699, at *11. As discussed below, there is nothing “exceptional” about this case warranting fees *precisely because* Healthier

Choices advanced a substantively strong litigation position when considering the governing law and facts of the case—and the Federal Circuit will necessarily address these same issues on appeal. As such, “prudence dictates awaiting the appellate court’s ruling, which ... will either support or undermine [Healthier Choices’] argument against the award of attorneys’ fees.” *Id.* And, even if the Federal Circuit ultimately affirms this Court’s decision—and to be clear, it should not—this could nonetheless assist the Court in resolving the Motion. *Sprint Commc’ns*, 201 F. Supp. 3d at 566 (explaining that “the Federal Circuit could affirm, and indicate—perhaps indirectly through what it writes—that this is a close case,” and thus, “deciding the issue in light of the decision on appeal is likely to make the decision easier and better”).

Nor will deferring resolution of the Motion cause prejudice to any party. The Court quickly resolved this case at the pleading stage, and “[m]otions for exceptional fees are often decided after much longer periods of litigation.” *Baggage Airline Guest Servs.*, 2019 WL 644827, at *2. Moreover, courts have found that deferring resolution of motions for attorneys’ fees *avoids* piecemeal litigation. *Bowers v. Universal City Dev. Partners, Ltd.*, 2005 WL 1243745, at *2 (M.D. Fla. May 19, 2005) (“If the district court were to resolve the fee and cost issue while an appeal remains pending, it would be asked to repeat the procedure following the appeal. This Court prefers to avoid the piecemeal resolution of fee disputes.”); *accord Elver v. Whidden*, 2019 WL 718536, at *2 (M.D. Fla. Feb. 20, 2019); *see also Corey*

Airport Servs., Inc. v. City of Atlanta, 2011 WL 13216938, at *1 (N.D. Ga. Apr. 6, 2011) (finding that “it would be an inefficient use of limited judicial resources to address the plaintiff’s motion for attorney’s fees” while an appeal is pending.).

Whether Defendants are entitled to exceptional fees necessarily hinges on their prevailing on the merits. There is simply no need for the Court to now resolve this contingent issue while an appeal is pending.

B. This is Not an Exceptional Case Warranting Attorneys’ Fees

There is nothing “exceptional” about this case. It is well established that a patent is presumed valid, *see Microsoft Corp. v. I4I Ltd. P’ship*, 564 U.S. 91, 100 (2011), and “there is a presumption that an assertion of infringement of a duly granted patent is made in good faith.” *Checkpoint Sys., Inc. v. All-Tag Sec. S.A.*, 858 F.3d 1371, 1376 (Fed. Cir. 2017) (internal quotations omitted). As such, “a patent holder has the right to vigorously enforce its presumptively valid patent.” *DietGoal Innovations, LLC v. Wegmans Food Markets, Inc.*, 126 F. Supp. 3d 680, 685 (E.D. Va. 2015) (brackets and citation omitted). Healthier Choices filed the Complaint and proposed Amended Complaint in good faith, seeking to do just that.

1. Healthier Choices’ Litigation Position Was—and Remains—Strong

Defendants’ *entire* basis for arguing that this case is “exceptional” rests on the flawed assertion that Healthier Choices’ litigation position was weak at the outset. (*See* Defs.’ Motion at 9–12.) Specifically, Defendants contend that because

Healthier Choices' claims were contradicted by Defendants' MRTPA, it should never have commenced this lawsuit to begin with. Thus, according to Defendants, the mere fact that they stated in an application to the FDA that no combustion takes place necessarily proves that no combustion can take place—irrespective of any testing to the contrary—and any patent holder that challenges that self-serving statement in court should be punished with attorneys' fees. Defendants' arguments defy both commonsense and basic principles in the Rules of Civil Procedure.

The substantive strength of Healthier Choices' litigation position was—and continues to be on appeal—strong and entirely reasonable. Healthier Choices alleged that the IQOS system infringes the '170 Patent because it initiates a combustion reaction, and even had independent testing confirm that the IQOS system *in fact* causes a combustion reaction. Notwithstanding, the *sole stated basis* for the Court dismissing this case was that it believed that it was bound to accept as true Defendants' own self-serving statements regarding a lack of combustion. That conclusion—and Defendants' assertions regarding the purported weakness of Healthier Choices' litigation position—are wrong as a matter of law, and for several reasons.

First, the Court erred in holding that the originally-filed Complaint could not contradict Defendants' self-serving statements, merely because they were attached to the Complaint as an exhibit. As the Seventh Circuit aptly explained:

Rule 10(c) does not require a plaintiff to adopt every word within the exhibits as true for purposes of pleading simply because the documents were attached to the complaint to support an alleged fact. A blanket adoption rule makes sense in the context of an attached contract or loan agreement because the contract represents an agreement between two or more parties to which the law binds them. We are not inclined to apply such a rule in the case of letters written by the opposition for what could be self-serving purposes.

N. Indiana Gun & Outdoor Shows, Inc. v. City of S. Bend, 163 F.3d 449, 455 (7th Cir. 1998); *accord Goines v. Valley Cmty. Servs. Bd.*, 822 F.3d 159, 168 (4th Cir. 2016) (“The purpose for which the document is offered is particularly important where the document is one prepared by or for the defendant. Such unilateral documents may reflect the defendant’s version of contested events or contain self-serving, exculpatory statements that are unlikely to have been adopted by the plaintiff. Treating the contents of such a document as true simply because it was attached to or relied upon in the complaint, even though the plaintiff relied on it for purposes other than truthfulness, would be contrary to the concept of notice pleading and would enable parties to hide behind untested, self-serving assertions.”) (internal quotations omitted); *accord Haskett*, 648 F. App’x at 496–97 (“it would be perverse to use [defendant’s] self-serving claims to reject [plaintiff’s] factual allegations,” merely because they were attached to the complaint); *Gant v. Wallingford Bd. of Educ.*, 69 F.3d 669, 674–75 (2d Cir. 1995) (explaining by analogy that “a libel plaintiff may attach the writing alleged in the complaint to be libelous without risk that the court will deem true all libels in it”); *Bandelet v. Wirbicki L. Grp., LLC*, 2021

WL 2105020, at *4–5 (N.D. Ill. May 25, 2021) (“The Court does not agree with defendants that plaintiff, by attaching the letter [to the complaint], has admitted the truth of every statement defendant included in the letter.”).

Courts in the 11th Circuit follow this same commonsense approach. *E.g.*, *Gill as Next Friend of K.C.R. v. Judd*, 941 F.3d 504, 514 (11th Cir. 2019) (“When a complaint contains specific, well-pleaded allegations that either do not appear in the attached exhibit or that contradict conclusory statements in the exhibit, we credit the allegations in the complaint.”); *Saunders v. Duke*, 766 F.3d 1262, 1270 (11th Cir. 2014) (where a plaintiff “attaches a police report to his complaint and alleges that it is false ... the contents of the report cannot be considered as true for purposes of ruling on a motion to dismiss”); *Guidry v. JP Morgan Chase Bank, N.A.*, No. 2:20-CV-01618-ACA, 2021 WL 3860961, at *1 (N.D. Ala. Aug. 30, 2021) (same).

Healthier Choices attached Defendants’ MRTPA to show that even Defendants’ *own testing* indicated that the IQOS system causes a combustion reaction—*contrary* to what Defendants stated in the rest of that exhibit. Likewise, Healthier Choices attached the FDA press release because it showed that PMP is the regulatory approval holder for the IQOS—not because Healthier Choices was adopting as true all of the statements in that press release. The Court’s decision resulted in precisely the “perverse” outcome that other courts have cautioned against—Defendants’ self-serving statements being credited over the specific, well-pleaded allegations in the Complaint.

Second, this error was compounded when the Court denied Healthier Choices leave to file the Amended Complaint—and despite that Defendants’ self-serving statements in the MRTPA were no longer included as exhibits. As a threshold matter (and contrary the Court’s findings), Defendants’ MRTPA and the FDA press release are not central to Healthier Choices’ patent infringement claims, and therefore should not have been considered in the first place. Healthier Choices alleged that each Defendant “makes, uses, offers to sell, or sells” a product that infringes the ’170 patent. *See* 35 U.S.C. § 271(a). Whether Defendants ever applied for or received FDA approval is immaterial to proving any element of infringement under § 271(a). *See In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) (“FDA approval ... is not a prerequisite for finding a compound useful within the meaning of the patent laws.”).²

But even setting that aside, it simply does not follow that because the Court believed it could *consider* Defendants’ self-serving statements in the MRTPA that it was therefore *required* to accept those statements as true and credit them *over* the specific contradictory allegations in the Amended Complaint. *See Hoefling v. City of Miami*, 811 F.3d 1271, 1277 (11th Cir. 2016) (“[O]ur cases do not permit a district court to consider, on a motion to dismiss, exhibits attached to an earlier complaint

² Likewise, neither Defendants’ MRTPA nor the FDA press release were *necessary* for Healthier Choices to allege personal jurisdiction over PMP. *See* Order Denying Leave to Amend at 11. The Amended Complaint alleges that “PMP manufactures and imports the accused infringing product into this District.” Am. Compl. ¶ 11. That allegation standing alone suffices for personal jurisdiction irrespective of whether PMP “was the regulatory approval holder.” *See id.*

that a plaintiff has expressly disavowed or rejected as untrue in a subsequent amended complaint.”). The Court effectively ruled that, once the Defendants’ statements were attached to the original Complaint, they could *never* be contradicted through an Amended Complaint.

Again, this led to a perverse outcome—crediting Defendants’ self-serving statements that the IQOS system does not cause combustion *over* the specific allegations in the Amended Complaint and testing conducted by Dr. Deible that the IQOS system does *in fact* initiate a combustion reaction. As it now stands, the Court’s Orders require that *any time* a defendant applies for FDA approval regarding a product that is alleged to infringe a patent, the defendant’s own version of the facts will be credited over the specific allegations in the complaint—irrespective of whether or not the plaintiff attaches those documents as exhibits. Such a result is unlikely to stand on appeal.³

³ Indeed, even the FDA’s later approval is immaterial to whether Healthier Choices’ pleadings plausibly allege that the IQOS system actually initiate a combustion reaction—as alleged in the Complaint and Amended Complaint for purposes of patent infringement. *See GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1331 (Fed. Cir. 2021) (“the FDA is not the arbiter of patent infringement issues”) (citation omitted); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002) (stating that the FDA’s “primary task” is “ensuring that drugs are safe and effective,” and recognizing that “the FDA has no expertise in making patent law judgments”); *Watson Pharms., Inc. v. Henney*, 194 F. Supp. 2d 442, 445 (D. Md. 2001) (explaining that the FDA “has no expertise—much less any statutory franchise—to determine matters of substantive patent law”). For this reason, this Court correctly observed that it “may not consider the substance of a scientific review conducted by the FDA that Defendants attach to their motion as confirmation

Whether the IQOS system initiates a combustion reaction was a question of fact for the factfinder, not a question for the Court to resolve at the pleading stage by weighing evidence or disregarding Healthier Choices’ specific and well-pled allegations. Likewise, it was also premature for the Court to resolve the parties’ dispute regarding construction of the term “combustion reaction.” Healthier Choices alleged that the term means “a chemical reaction that requires fuel, oxygen and an ignition source.” Am. Compl. ¶ 47. Healthier Choices further alleged that its independent testing indicates that “the IQOS® system generates combustion markers, including carbon monoxide and carbon dioxide, in sufficient quantities to indicate that combustion occurs in the IQOS® system,” and does so “at temperatures at or below 350°C.” *Id.* ¶¶ 48–49. Healthier Choices claim construction is materially different than Defendants’ overly narrow definition of combustion that it provided to the FDA, i.e., that a combustion process means “burning *and the formation of smoke with solid particles and high level of HPHCs.*” Although there is no disagreement that “‘combustion reaction’ means that *some sort* of combustion must occur” (Order Granting Motion to Dismiss at 19) (emphasis added), the parties plainly disagree on what the term “combustion” means. As a result, by finding that

that combustion does not occur.” Order Granting Motion to Dismiss at 13 n.2. The FDA has neither the expertise nor the statutory authority to determine whether a combustion reaction occurs for purposes of the patent infringement issues. But as explained above, the Court’s Orders have gone even beyond that and treated Defendants’ mere *application* to the FDA as conclusive for purposes of patent infringement issues.

the Amended Complaint was futile, the Court necessarily resolved the claim construction dispute between the parties as to the meaning of “combustion”—and did so in Defendants’ favor, which “was particularly inappropriate in the Rule 12(b)(6) context.” *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1349 (Fed. Cir. 2018). In addition, the Court neither accepted the factual allegations set forth in the Amended Complaint concerning Healthier Choices’ independent testing confirming combustion in the IQOS system as true nor did it construe the Amended Complaint in the light most favorable to Healthier Choices, which is also inappropriate at the pleading stage. Healthier Choices’ amendments to the Complaint were not futile, and its litigation positions have been consistently reasonable.

In any event, “a strong or even correct litigating position is not the standard by which [courts] assess exceptionality.” *Stone Basket Innovations*, 892 F.3d at 1180. Rather, the relevant inquiry in determining the strength of Healthier Choices’ litigation position is whether it was *reasonable*. *Munchkin, Inc.*, 960 F.3d at 379. For the reasons discussed above, it was plainly reasonable for Healthier Choices to believe that the specific allegations in its pleadings that the IQOS initiates a combustion reaction—as confirmed by Dr. Deible’s independent testing—should be accepted as true, and that Defendants’ self-serving statements in an application would not be deemed irrefutable.

2. *Healthier Choices' Litigation Conduct Is Not Exceptional*

Defendants fail to identify any litigation conduct by Healthier Choices that would warrant a finding this is an “exceptional” case. This has been a straightforward case where Healthier Choices has at all times conducted itself reasonably.

There has been nothing unreasonable about Healthier Choices’ litigation conduct. This is not a case where Healthier Choices is alleged to have “committed a pattern of litigation abuses,” by filing repeated patent infringement actions “for the sole purpose of forcing settlements, with no intention of testing the merits.” *Stone Basket Innovations*, 892 F.3d at 1183. To the contrary, Healthier Choices has clearly demonstrated every intention of prosecuting its claims and reaching the merits. Nor is this a case of where Healthier Choices presented “shifting case theories” that may otherwise warrant attorneys’ fees. *See Rothschild Connected Devices Innovations, LLC v. Coca-Cola Co.*, 2019 WL 10377759, at *2–3 (N.D. Ga. Aug. 12, 2019). Here, Healthier Choices has consistently alleged that the IQOS system initiates a combustion reaction that infringes the ’170 patent, notwithstanding Defendants’ self-serving assertions to the contrary. Nor is this a case where Healthier Choices failed to perform “a reasonable pre-filing inquiry.” *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1302 (Fed. Cir. 2004). Healthier Choices plainly went beyond performing the requisite “infringement analysis,” *see id.*, having conducted independent testing that *confirms* the IQOS system initiates a combustion reaction.

Healthier Choices believing that its own specific allegations and independent testing should be accepted as true at the pleading stage is not unreasonable—it is required by the law.

3. *The Cases Relied on By Defendants Are Inapposite*

The cases that Defendants rely on to suggest that this is an exceptional case warranting attorneys’ fees are plainly inapposite—even a cursory review quickly demonstrates that they bear no resemblance to this case. Healthier Choices addresses them each briefly below.

In *Blackbird Tech LLC v. Health In Motion LLC*, 944 F.3d 910 (Fed. Cir. 2019), for example, the plaintiff’s manner in litigating the case was unreasonable for a host of reasons—including the fact that it made “a series of decreasing settlement offers” that the Federal Circuit described as “nuisance value” (*id.* at 916); committed a series of discovery abuses, including delaying production of documents and failing to produce responsive documents (*id.* at 917); and filed a notice of dismissal and covenant not to sue on the eve of trial without even notifying opposing counsel (*id.*). *On top of that*, the plaintiff’s claim construction and infringement contentions were plainly flawed on their face. *Id.* at 915–16. None of these facts are present here.

Similarly, in *Lumen View Tech. LLC v. Findthebest.com, Inc.*, 811 F.3d 479, the Federal Circuit upheld the lower court’s finding that the case was exceptional where it found: the plaintiff’s “motivation for filing suit was to extract a nuisance settlement” (*id.* at 481); that its “‘predatory strategy’ of baseless litigation showed

the need for deterrence” (*id.* at 481–82); *and* the “suit was frivolous and objectively unreasonable” because the patent required “the preference data of two or more parties” but a pre-suit investigation would have shown that the accused product “only used the preference data of one party.” *Id.* at 481. Again, *none* of these facts are present here, particularly in light of the testing conducted by Healthier Choices.

In *Eltech Sys. Corp. v. PPG Indus., Inc.*, 903 F.2d 805 (Fed. Cir. 1990), the lower court “painstakingly detailed on three pages” a litany of reasons why it found that the plaintiff acted in bad faith in maintaining its suit. *Id.* at 810.⁴ The long and detailed account of the plaintiff’s *unreasonable* conduct in *Eltech Systems* stands in sharp contrast to the facts of this case—and in fact, illustrates how just far removed this case is from one in which attorneys’ fees are actually warranted under § 285.

In *AdjustaCam, LLC v. Newegg, Inc.*, 861 F.3d 1353 (Fed. Cir. 2017), the Federal Circuit found this case as “standing out from others” because the plaintiff maintained a baseless lawsuit for over *five years*. *Id.* at 1360. The Federal Circuit explained that although the plaintiff initially “may have filed a weak infringement lawsuit . . . [the] suit became baseless after the district court’s *Markman* order.” *Id.*

⁴ Those reasons for finding the case exceptional included, *inter alia*, “findings that the patentee conducted insufficient tests to establish whether there was infringement;” the patentee “withh[olding] its expert’s opinion as privileged, thus supporting an inference that the report was not favorable to the patentee;” and “[t]he patentee justified its filing and continuance of the infringement action on the basis of oral advice of counsel which was unsupported by technical or legal analyses.” *Sentex Sys., Inc. v. Elite Access Sys., Inc.*, 250 F.3d 756 (Fed. Cir. 2000) (citing *Eltech Sys. Corp.*, 903 F.2d at 808, 810–11).

Notwithstanding, the plaintiff “continued to press baseless infringement contentions well past an adverse *Markman* order and expert discovery.” *Id.* at 1362. *On top of that*, the plaintiff also litigated the case in an unreasonable manner, through “repeated use of after-the-fact-declarations,” “filing new declarations ... without disclosing them as new on appeal,” asserting “nuisance-value damages against many defendants” and “settl[ing] with them for widely varied royalty rates.” *Id.* at 1361–62. Again, none of these facts that made *AdjustaCam* “stand out” are present here.

In *Rothschild Connected Devices Innovations, LLC v. Guardian Prot. Servs., Inc.*, 858 F.3d 1383 (Fed. Cir. 2017), the plaintiff was willfully ignorant of the prior art—submitting affidavits conceding that it had not even “conducted an analysis of the prior art . . . to form a belief as to whether the prior art would invalidate” the patent at issue. *Id.* at 1388. *On top of that*, the plaintiff engaged in vexatious litigation practices, settling numerous prior lawsuits for nuisance value. *Id.* at 1389–90. Based on the totality of these circumstances—which are not present here—the case was exceptional.

Finally, in *Bayer CropScience AG v. Dow AgroSciences LLC*, 851 F.3d 1302 (Fed. Cir. 2017), the plaintiff’s litigation position was weak because it “marched onward with a view of its case that was not supported by its witnesses” and “the district court permissibly relied on the testimony of [plaintiff’s] witnesses to discredit [plaintiff’s] interpretation.” *Id.* at 1307. *On top of that*, the plaintiff filed a “motion for preliminary injunction nearly eighteen months after alleging

infringement”—while the parties were conducting depositions that included testimony from plaintiff’s “own witnesses that debunked plaintiff’s claims”—which “unnecessarily increased the costs of litigation and was a factor for deeming this case exceptional.” *Id.* at 1307–08 (internal quotation marks omitted). This case is markedly different—the only “evidence” that contradicts the claims is Defendants’ own self-serving statements. *Bayer CropScience* has no application here.

At bottom, Defendants’ contentions amount to little more than a request for a punitive imposition of attorneys’ fees because Healthier Choices’ case was dismissed at the pleadings stage. The Court should “not award attorney’s fees as a penalty for failure to win a patent infringement suit.” *Munchkin, Inc.*, 960 F.3d at 1378 (internal quotations omitted). There is nothing exceptional about this case. *See FireBlok IP Holdings, LLC v. Hilti, Inc.*, 855 F. App’x 735, 739 (Fed. Cir. 2021) (rejecting defendant’s arguments that the case was “exceptional because [plaintiff’s] arguments were weak and frivolous” and upholding district court’s denial of attorneys’ fees); *ATEN Int’l Co. v. Uniclass Tech. Co.*, 932 F.3d 1371, 1374 (Fed. Cir. 2019) (upholding denial of attorneys’ fees, notwithstanding that plaintiff “presented a weak case for lost profits that relied on guesswork”); *Sarif Biomedical LLC v. Brainlab, Inc.*, 725 F. App’x 996, 999 (Fed. Cir. 2018) (“The District Court’s ultimate disagreement with [plaintiff’s] proposed construction does not, on its own, render [plaintiff’s] case substantively weak.”); *Cap. Sec. Sys., Inc. v. NCR Corp.*, 2018 WL 300549, at *4 (N.D. Ga. Jan. 5, 2018) (finding that case was not

exceptional notwithstanding “former counsel’s recusal based, in part, on perceived fraudulent conduct,” and explaining the fact that the defendant “prevailed on the claim construction and summary judgment motions is insufficient to demonstrate Plaintiff pursued the case without a reasonable belief that it had merit”).

C. Healthier Choices Reserves the Right to Object to the Reasonableness of the Fees Defendants Requested

Defendants’ Motion requests an exorbitant award of \$639,043 for a case that was quickly resolved at the pleading stage. However, Defendants delayed filing a detailed specification and itemization of the requested award and other supporting documentation until after close of business on January 18, 2022—that is, the evening before Healthier Choices filed this Opposition. As a result, Healthier Choices has not had sufficient time to evaluate the reasonableness of the requested award. With the Court’s permission, Healthier Choices will respond in a supplemental filing. *See Am.’s Home Place, Inc. v. Fine Built Constr. of N. Carolina, Inc.*, 2018 WL 11356323, at *3 (N.D. Ga. Apr. 25, 2018) (allowing plaintiff to file objections to the itemization of the requested fees within 14 days of the defendants’ submission).

V. CONCLUSION

For the foregoing reasons, Healthier Choices respectfully requests that the Court defer ruling on Defendants’ Motion pending the outcome of the appeal and dismiss the Motion without prejudice, or alternatively, deny the Motion because this is not an exceptional case warranting attorneys’ fees.

Dated: January 19, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to LR 7.1(D) the undersigned hereby certifies that the foregoing document has been prepared in Times New Roman, 14 point, one of the four fonts and points approved by the Court in L.R. 5.1C.

/s/ Alycen Moss
Alycen Moss

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on January 19, 2022, the foregoing document was filed with the Clerk of the Court using CM/ECF, which will send electronic notification of such filing to all counsel of record.

/s/ Alycen Moss
Alycen Moss